

**REMARKS**

Reconsideration of the above-identified application in view of the preceding amendments and the following remarks is respectfully requested.

Claims 1-4, 6-23 and 25-50 are pending in this application. Claims 40-45 have been withdrawn from consideration as being directed to non-elected subject matter. Claims 5 and 24 have been cancelled without prejudice. By way of this amendment Claims 1-3, 9, 11, 12, 15, 18, 20, 31, 39, 46 and 48-50 have been amended to more particularly point out and define the subject matter regarded as inventive. Support for the aforementioned amendments can be found throughout Applicant's specification.

In particular, each of the independent claims have been amended to clarify that the invention, as presently claimed, is directed to, among other things, a diagnosis and treatment system that can provide rapid treatment of a tissue area by automatically detecting and treating subsurface targets within the tissue area. As discussed in more detail below, it is respectfully submitted that all of the claims now pending in this application are patentable over the art of record and are therefore in condition for allowance.

Claim Rejections – 35 U.S.C. §103

Claims 1-4, 6-23, 25-39 and 46-50 were rejected under 35 U.S.C. §103(a) over U.S. Patent No 5,860,967 to Zavislan et al. (“the ‘967 patent”) in view of U.S. Patent No. 5,071,417 to Sinofsky (hereinafter, “the ‘417 patent”). Applicant respectfully traverses the rejections.

The ‘967 patent discloses a hand held microsurgical instrument for applying laser energy to a selected location in an area under the skin. The area is visualized through a video processing system while the laser beam is steered by a steering device 28. A controller and video processing unit designated by reference numeral 24 obtains signals from the beam steering device 28 and applies them to a beam deflection system utilizing mirrors and motors which step or steer the beam in X and Y directions. (See col. 4, lns. 32-34). The controller 24 functions to position the laser beam at a desired location, so that it can be focused to a depth that will avoid damage to the tissue above the treatment site. The ‘967 patent describes that this system is generally a manual system that a surgeon can use to treat a patient:

When the area has been found the shutter is moved so that the incoming beam is intercepted at region b, containing a neutral density filter which attenuates the laser beam in the path of the output beam from the coupler 66. The region 2 is then in the path of the return light from the spot where the laser beam is focused in the treatment plane. The region 2 may be an open hole. This permits both visible viewing and viewing of the infrared (700 to 1300 nm wavelength illumination) due to the laser beam. In this position of the shutter the system utilizes the laser beam as a spotter or tracking beam to locate the sites to be treated, say a hair follicle or a part of a spider vein to be coagulated, or an adhesion between a tendon and its sheath.

Finally, the shutter is moved to its furthest position (in a counter clockwise direction in FIG. 5) about the axis 70 of rotation of the shaft 75 of the motor 74. Then, the output beam 66 passes through an open hole c, while a neutral density filter (region 3) is interposed in the return path to protect the television camera (especially the CCD sensor array) during the treatment pulse.

(‘967 patent, Col. 7, lines 30-50). As can be seen, the system of the ‘967 patent uses a laser to illuminate an area of the tissue under low laser power to enable a surgeon to visually identify an area to be treated (e.g., hair follicle or vein). The operator then makes a decision to apply a treatment pulse to the area. As can be seen, this process is not contemplated as automatic, but requires an operator to make a reasoned decision as to whether to apply a treatment pulse.

The ‘417 patent discloses an apparatus for joining biological materials by laser fusion including a laser for delivering a beam of radiation to an anastomotic site, a reflectance sensor for measuring the intensity of infrared light reflected from the site while illuminating the site by a light source, a monitor connected to the reflectance sensor for monitoring changes in the intensity of infrared light reflected from the site, analyzing means connected to the monitor to determine the degree of crosslinking or coagulation of the biological materials based upon the monitored changes and for generating a signal representative of the degree of crosslinking to determine when an optimal state of fusion has occurred, and control means connected to the analyzing means and laser for controlling the output of the laser in response to the crosslinking signal. More specifically, the degree of cross linking is monitored by applying a second light source, and monitoring the reflections of the second light source to determine the degree of cross-linking. (e.g., ‘417 patent, Col. 4, lines 35-55).

In contrast, independent Claims 1, 20, 39, 46 and 48-50, as currently amended, define methods and apparatus for the selective laser treatment of a tissue surface area which involves, *inter alia*, automatically determining a location and one or more characteristics for one or more subsurface targets based upon one or more reflections detected by a photo-sensor and predetermined conditions, wherein the predetermined conditions are defined at least in part by

one of predetermined image analysis and one or more preprogrammed mathematical treatment algorithms that relate to features of an image, for example, geometric features or properties of an image, such as, algorithms relating to the differential geometric properties of an image, *e.g.*, a line detection algorithm or the like.

Prior art systems of the type disclosed in the '967 patent are typical of systems that depend on "selective photothermolysis" to operate that Applicant has already distinguished in its patent application:

A further advantage of the Smart Scalpel system of the present invention is that the kinds of treatment that it can perform is not constrained by the characteristics and parameters of the treatment system (*e.g.*, laser treatment wavelengths) as it would be in a conventional laser device that does not "aim." In other words, the concept of selective photothermolysis for target treatment is not critical to the Smart Scalpel system of the present invention. This is because the treatment system is also spatially selective.

(Specification at ¶ 84).

Stated another way, the teachings of the '967 patent are inapposite to the invention as presently claimed which provides rapid treatment of a tissue area by automatically detecting and treating subsurface targets within the tissue area. The claimed process and system can be fully or partially automatic. The system of the '967 patent teaches a system that requires an operator to make a reasoned decision as to whether to apply a treatment pulse – there is no suggestion of diagnosing and treating the tissue automatically based on predetermined conditions, let alone measuring one or more characteristics indicative of the physio-chemical properties to automatically identify each of the targets as claimed in amended claimed 1.

As discussed above, the '417 patent is directed to a laser anastomosis system. This system utilizes a fusion laser that is adapted and configured to cause crosslinking of a biological

glue 36. The degree of crosslinking is monitored by applying a second light source, and monitoring the reflections of the second light source to determine the degree of cross-linking. (e.g., '417 patent, Col. 4, lines 35-55).

Applicant respectfully submits that there is no motivation for combining the teachings of the '967 patent with the '417 patent for at least the following reasons. First, the systems are configured to achieve nearly opposite objectives – the destruction of tissue in the '967 patent versus the preservation and fusing of tissue in the '417 patent. Moreover, the reflectance monitoring system of the '417 patent is adapted and configured to indicate the degree of crosslinking of a biological glue – there is no teaching or suggestion to modify this system to compare the light with predetermined conditions indicative of pre-existing tissue to be ablated. Thus, incorporating the reflectance monitoring system of the '417 patent into the system of the '967 patent can not arrive at Applicant's claimed invention. Indeed, modifying the reflectance monitoring system of the '417 patent to function in a manner similar to Applicant's claimed invention would require changing the principle of operation of the reflectance monitoring system in the '417 patent and therefore "renders the prior art unsatisfactory for its intended purpose." MPEP §2143.01. This is powerful evidence of the non-obviousness of the invention as presently claimed.

Moreover, the rejections of record necessarily "include knowledge gleaned only from applicant's disclosure" - whole elements of Applicant's claimed invention are missing from the prior art. Any attempt to fill in those gaps using Applicant's disclosure is therefore impermissible hindsight. MPEP § 2145(X)(A). Thus, Applicant respectfully submits that no

prima facie case of obviousness has been established with respect to Applicant's claimed invention.

It is respectfully submitted that neither of the references cited by the Examiner in support of the rejection under 35 U.S.C. §103(a) disclose or suggest, either alone or in combination, in whole or in part, the subject matter defined by the amended claims of the subject application. In particular, neither the '967 patent nor the '417 patent disclose or suggest, either a system or method of selective laser treatment of a tissue surface area which involves, *inter alia*, automatically determining a location and one or more characteristics for one or more subsurface targets based upon one or more reflections detected by a multi-dimensional photo-sensor and predetermined conditions, which are defined by either predetermined image analysis or one or more mathematical treatment algorithms that relate to features of an image, for example, a line detection algorithm.

Therefore, it is submitted that Claims 1, 20, 39, 46 and 48-50, and each of the claims depending respectively therefrom are not rendered obvious by the combination of the '967 patent and the '417 patent. Accordingly, withdrawal of the rejections under 35 U.S.C. §103(a) is respectfully requested.


Formal Request For Interview

Applicant respectfully requests an interview with the Examiner to discuss the present application and the prior art of record. Applicant's attorney of record Brian Pollack may be reached at (203) 353-6876 to schedule a mutually convenient date and time and to provide assistance or additional information if required.

It is respectfully submitted that each of the claims now pending in this application, namely Claims 1-4, 6-23, 25-39 and 46-50, are directed to patentable subject matter, and allowance thereof is earnestly solicited. The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 04-1105, under Order No. 62001 (51588).

Respectfully submitted,

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